UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,066	12/18/2001	Loren J. Field	7037-450	3713

7590 02/08/2005

Kenneth A. Gandy
Woodard, Emhardt, Naughton, Moriarty & McNett
Bank One Center/Tower, Suite 3700
111 Monument Circle
Indianapolis, IN 46204-5137

EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,066	FIELD ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-28,43-45 and 49-84* is/are pending in the application.

4a) Of the above claim(s) *43-45 and 63-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28,49,50 and 53-62* is/are rejected.

7)☒ Claim(s) *51 and 52* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Paper filed 22 November 2004 in reply to the Non-Final Office Action mailed 18 May 2004. Claims 1-19 and 29-48 were withdrawn from consideration and claims 20-28 were considered in the 18 May Office Action. Claims 1-19, 29-42 and 46-48 were canceled, claims 20-22 were amended and claims 49-84 were added in the 22 November Paper. Claims 20-28, 43-45 and 49-84 are pending. Claims 43-45 stand withdrawn from consideration.

Election/Restrictions

Newly submitted claims 63-84 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The elected invention of Group II is related to newly filed claims 63-84 as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as in a microarray assay for determining the effect of cyclin D2 overexpression on cardiomyocyte gene expression or to isolate genes induced by cyclin D2 overexpression.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 63-84 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 20-28 and 49-62 are presently under consideration.

Response to Amendment

Claim Objections

Objection to claim 20 is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112

Claims 20-28 stand rejected and newly added claims 49, 50 and 53-62 are rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claims for reasons of record and herein below in the response to arguments.

Rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of the amendment of the claim such that it no longer contains the "corresponding to" language and in view of the clarification of "substantial identity" in the remarks filed in the 22 November Paper. In the paragraph bridging pages 13-14 of the Remarks, Applicant states, "'substantial identity' encompasses proteins that differ from the native D2 protein but which are sufficiently identical to exhibit the characteristic cyclin D2 activity as

identified in the application..." According to this, substantial identity is understood to encompass any polypeptide that exhibits a cyclin D2 activity, as any polypeptide that exhibits the activity must be sufficiently identical in structure. As pointed out in the previous Office Action, the specification provides no limiting definition of what constitutes cyclin D2 activity. Therefore, according to the broadest reasonable interpretation, the cyclin D2 protein of the claims encompasses any protein having some activity in common with the proteins comprising SEQ ID NO: 2 or SEQ ID NO: 4.

Claim Rejections - 35 USC § 102

Claims 20, 21, 23, 24, 26 and 27 stand rejected and new claims 49 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Soonpa *et al.* (1997) *J. Clin. Invest.* 99:2644-2654 as evidenced by Lahti *et al.* (1997) *J. Biol. Chem.* 272: 10859-10869 for reasons of record and herein below in the response to arguments.

Response to Arguments

Claim Rejections - 35 USC § 112

Claims 20-28, 49, 50 and 53-62 are rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter. As stated in the previous Office Action, the specification, while being enabling for a cardiomyocyte having an introduced nucleic acid encoding a cyclin D2 protein comprising SEQ ID NO: 2, SEQ ID NO: 4 or the sequence of a mouse cyclin D1 protein as described by Soonpa *et al.* (1997) *J. Clin. Invest.* 99:2644-2654, does not reasonably provide enablement for a cardiomyocyte cell having

introduced a nucleic acid encoding any protein having cyclin D2 activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In response to the *prima facie* case of record, Applicant characterizes the relevant facts as follows:

1) "[T]he degree of ordinary skill in the relevant field is high". While this is acknowledged, the scope of the claims is so broad and the art is so unpredictable that even one of extraordinary skill would not be able to make the full scope of the operative embodiments within the scope of the claims without undue experimentation. As established in the previous Office Action, the art recognizes even minor changes in protein structure can have dramatic effects on function. Also as discussed in the previous Office Action and herein above, the broadest claims encompass any polypeptide having some activity in common with the proteins comprising SEQ ID NO: 2 or SEQ ID NO: 4 and thus encompass a vast array of structurally and functionally divergent polypeptides. By way of further illustration, one can calculate the number of possible amino acid sequence combinations within a given sequence identity of a reference sequence using the formula $\frac{x^n \times L!}{n! \times (L-n)!}$, wherein x=the number of possible substitutions (*i.e.*, 19 naturally occurring amino acids), n= the maximum number of variant positions and L=the length of the sequence. According to this formula a genus of polypeptides having at least 95% sequence identity with a polypeptide consisting of 100 amino acids comprises nearly 2×10^{14} possible combinations. The instant SEQ ID NO: 2 and 4 each consist of 289

amino acids and, therefore, even if one were to limit the sequence to 95% sequence identity, which it is not, the genus would be many orders of magnitude greater than the hypothetical 100 amino acid protein. Given this scope and the art recognized unpredictability, the skilled artisan simply would not know how to use the full scope of what is claimed and would not be able to identify the useful embodiments without undue experimentation.

2) "[T]he sequences involved are known, and were known for some time prior to the filing date". This is true only for the sequences set forth as SEQ ID NO: 2 and 4 and the sequence of a mouse cyclin D1 protein as described by Soonpa *et al.*, which are acknowledged to be within the enabled scope. The other sequences within the scope of the claims, which make up the vast majority of polypeptides having a cyclin D2 activity, were and are unknown.

3) "[T]he relevant art had developed with regard to functional domains of the sequences involved as of the filing date of the application". It is unclear what applicant is referring to in this statement because no specific studies are cited. However, enablement for the full scope of the instant claims would require that the skilled artisan know which structural elements confer D2 function, as it is broadly encompassed by the claims, such that the knowledge available would enable the skilled artisan to make and use a genus that bears a reasonable resemblance to the scope of the genus claimed.

4) "[T]he specification identifies for the skilled artisan not only (i) a variety of substitutions...but also (ii) domains that differ among cyclin D2 and cyclins D1 and

D3 to assist the skilled artisan in making polypeptides that retain the characteristic cyclin D2 activity...and (iii) distinct, characterizing functions of cyclin D2". However, the teachings referred to merely discuss general knowledge with regard to conservative amino acid substitution, suggest that phosphorylation sites can be deleted or various chimeric proteins might be constructed, describe putative phosphorylation sites comprised within the cyclin D1, D2 and D3 proteins and regions of relatively low sequence homology between cyclin D2 and the cyclin D1 and D3 proteins. These teachings amount to no more than a suggestion as to where the skilled artisan might start searching for useful embodiments within the scope of the claims. The majority of the claims do not limit the cyclin D2 protein to having any particular structure and those that do, for example claim 55, which requires that the amino acid sequence is at least 90% identical to amino acid residues 200 to 280 of SEQ ID NO: 2 or 4, are still not disclosed in sufficient detail to enable the skilled artisan to distinguish the operative embodiments from those that are inoperative without undue empirical experimentation. The application discloses that cyclin D1 does not confer the ability to maintain DNA synthesis in response to treatment with isoproterenol and differs substantially from the cyclin D2 amino acid sequence at residues 200-240 and 260-280. Based on this, Applicant appears to assume that the structural basis for the different function lies in the region of amino acids 200-280. While this might be a reasonable hypothesis, it is not a teaching of how to make what is claimed. There is no evidence that the structural requirements for maintain DNA synthesis in response to treatment with isoproterenol actually lie within amino acids

200-280 of the native cyclin D2 protein and not within some other region of structural divergence. Furthermore, even if some elements did lie within this region, the skilled artisan does not know if these elements are operative in any context other than the native cyclin D2 protein and does not know which portion of this region contains the required functional elements. Therefore, identifying the operative embodiments within even relatively narrow claims would require undue experimentation.

Applicant urges that the skilled artisan seeking to practice the invention would not attempt to compile a list of all possible differing sequences that could possibly satisfy the structural and functional features and then test all sequences in the list for functionality. Instead, one would begin with a reference sequence set forth in the specification, assess what changes could be made with an expectation of success and perform routine procedures to determine whether the sequence has the characteristics described and claimed in the application. Applicant concludes, "very little experimentation would be required for a person of ordinary skill in the art to identify a number of changes that could be made to a disclosed reference sequence that would not be expected to eliminate the functionality of the encoded protein and then to test the resulting polynucleotide or protein to confirm activity.

This argument has been fully considered but is not deemed persuasive. Applicant appears to be asserting that, because it would not require undue experimentation to identify some of the enabled embodiments within the scope of the claims, the claims are fully enabled. Applicant is again reminded that the enabled scope must bear a reasonable resemblance to that which is claimed. . "Although not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed

invention without 'undue experimentation.'" Vaeck, 947 F.2d at 495, 20 USPQ2d at 1444; Wands, 858 F.2d at 736-37, 8 USPQ2d at 1404; In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (the first paragraph of section 112 requires that the scope of protection sought in a claim bear a reasonable correlation to the scope of enablement provided by the specification)." In re Wright (CAFC) 27 USPQ2d 1510 at 1513. While making some embodiments within the scope of the claims might not require undue experimentation, given the vast scope of the claims and the general unpredictability of the art, determining which embodiments within the scope of the claims are operative such that one of ordinary skill would be able to make the full scope of the claimed invention, or some scope that bears a reasonable correlation thereto, would require undue experimentation.

Finally, Applicant alleges that the molecular modeling software available at the time of filing would also assist a person of ordinary skill in predicting the effects of amino acid changes in carrying out the claimed invention. This argument is not persuasive because, while these programs might assist the skilled artisan in identifying mutations that maintain a particular three dimensional structure, the skilled artisan does not know what structural features are required for cyclin D2 function, other than the structure of native cyclin D2 itself. To make the full scope of the claimed invention, the skilled artisan must know which structures can be altered and which structures cannot be altered to provide a polypeptide having a cyclin D2 activity. Such information was not available at the time of filing. It is also worth noting that all of the papers cited by Applicant as teaching molecular modeling software were published prior to Richards *et al.*, cited on page 5 of the previous Office Action, who teaches, "[e]ven the small changes are so complex that the linkage relations do not allow assignments of the energetic changes to unique

parts of the altered residue and its immediate contacts" and "[a]lmost all mutations are accompanied by some conformational change, making prediction of the effects on stability difficult." (cited on page 6 of the 18 May Office Action). Thus, Richards *et al.* teaches that predicting the effects of mutations on protein conformation and stability was considered difficult in spite of the technology available at the time.

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole; therefore, the claims are rejected under 35 USC §112, first paragraph as lacking enablement for the full scope of the claims.

Claim Rejections - 35 USC § 102

Claims 20, 21, 23, 24, 26, 27, 49 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Soonpa *et al.* (1997) *J. Clin. Invest.* 99:2644-2654 as evidenced by Lahti *et al.* (1997) *J. Biol. Chem.* 272: 10859-10869.

As stated in the previous Office Action, Soonpa *et al.* teaches a cardiomyocyte cell having an introduced nucleic acid encoding a cyclin D1 protein. As the cyclin D2 protein of the instant claims is construed to encompass any protein having cyclin D2 activity and Lahti *et al.* demonstrates that cyclin D1 and cyclin D2 have overlapping activity (see especially the paragraph bridging the left and right columns on page 10864), the cyclin D1 protein of Soonpa *et al.* meets the limitations of the cyclin D2 of the instant claims.

It is noted that, although claims 49 and 50 recite a structural limitation, the claim requires only that the nucleic acid molecule encoding a cyclin D2 protein have "a nucleotide sequence of nucleotides 4 to 870 of SEQ. ID. NO. 1 [or 3]". Absent evidence to the contrary, the broadest

reasonable interpretation of a nucleotide sequence of nucleotides 4 to 870 of SEQ ID NO: 1 or 3 is any nucleotide sequence comprised within that sequence (*i.e.*, any two or more nucleotides). As all polypeptide encoding nucleic acids comprise at least the sequence ATG, the nucleic encoding the polypeptide of Snoopa *et al.* would comprise this sequence, as do the sequences of the claims. Therefore, the teachings of Snoopa *et al.* anticipate the claims.

In response to the *prima facie* case of record, Applicant points out that the cyclin D2 protein of the claims has been construed as encompassing the native cyclin D1 protein and urges that it is inconceivable that such a conclusion could be reached because the application goes out of its way to distinguish cyclin D2 proteins from cyclin D1 proteins. This argument has been fully considered but is not deemed persuasive because as pointed out in the previous Office Action, the disclosure does not set forth a limiting definition of cyclin D2 protein, such that what is termed a cyclin D1 protein in the art would be excluded from the claims. Although the specification does identify functional differences between cyclin D1 and D2 proteins, the rejected claims do not require that the cyclin D2 protein exhibit those functions that distinguish it from a cyclin D1 protein. The specification and Applicant's arguments clearly indicate, the cyclin D2 protein of the claims embraces structurally and functionally diverse proteins and the art recognizes that the native cyclin D1 and D2 proteins exhibit overlapping functions. Therefore, absent some clear statement in the specification of what is excluded from the definition of a cyclin D2 protein, it is understood that any polypeptide having properties of a cyclin D2 protein would fall within the scope. Therefore, the claims are anticipated by the teachings of Soonpa *et al.*

New Grounds Necessitated by Amendment

Claim Objections

Claims 51 and 52 are objected to because of the following informalities: The claims recite "said nucleic acid molecule said introduced nucleic acid molecule" which is redundant and appears to be a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53, 54 and 55-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

In the instant case, the claims are directed to a cardiomyocyte cell having an introduced nucleic acid sequence that has a nucleotide sequence of nucleotides 4 to 870 of SEQ ID NO: 1 or 3, or having a sequence that will hybridize to a nucleotide sequence thereof under stringent conditions or that encodes a polypeptide having at least an amino acid sequence of SEQ ID NO: 2 or 4, wherein the protein encoded by the nucleic acid exhibits cyclin D2 activity so as to confer upon the cardiomyocyte an ability to maintain DNA synthesis in response to treatment with isoproterenol. Regarding the structural limitations of the claims, as discussed above, reference to a disclosed nucleic acid or amino acid sequence using an indefinite article is considered open to any sequence comprised within the full length sequence (*i.e.*, any two contiguous nucleotides or amino acids). If applicant intends that a nucleic acid or polypeptide be limited to comprising the entire sequence disclosed in a SEQ ID NO, the definite article should be used to refer to the sequence.

With regard to "stringent conditions", the disclosure provides no limiting definition of the term (page 12, third full paragraph). The art recognizes a range of conditions as "stringent", which require varying degrees of sequence homology for hybridization. As the claims must be afforded their broadest reasonable interpretation, the stringent conditions of the claims is understood to encompass very low stringency conditions, which conditions allow hybridization to sequences having low structural identity. Thus, the nucleic acid of the claims embraces molecules of highly divergent structure.

The Guidelines for Written Description state: "when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus" (Federal Register, Vol. 66, No. 4, Column 3, page 1106). "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus" (MPEP §2163(3)(a)(ii)).

The instant application discloses nucleic acids encoding two closely related species of polypeptides that exhibits cyclin D2 activity so as to confer upon the cardiomyocyte an ability to maintain DNA synthesis in response to treatment with isoproterenol (*i.e.*, SEQ ID NO: 2 and 4). These two species alone clearly are not representative of the full scope of the claims. With regard to relevant identifying characteristics, the specification discloses only that cyclin D1 and D3 do not confer upon the cardiomyocyte an ability to maintain DNA synthesis in response to treatment with isoproterenol and that amino acids 200-280 of the native cyclin D2 are significantly different from sequence found in the native D1 and D3 proteins. However, given no more than this, the skilled artisan could, at best, hypothesize that at least one element necessary to confer upon the cardiomyocyte an ability to maintain DNA synthesis in response to treatment with isoproterenol lies within this region. However, there is no direct evidence that the structure of amino acids 200-280 of the native cyclin D2 protein or any subsequence thereof is in any way involved in conferring the resistance to isoproterenol treatment. Furthermore, even if one could

assume that an element required for isoproterenol resistance is comprised within amino acids 200-280, there is no evidence that this region of the native cyclin D2 protein is sufficient to confer the recited property and, even if it were sufficient, the polypeptide encoded by the nucleic acid of the claims is not limited to comprising this structure. The specification clearly fails to disclose the relevant identifying characteristics of the claimed genus because the skilled artisan would not be able to distinguish what is claimed, (*i.e.*, nucleic acids encoding polypeptides that confer an ability to maintain DNA synthesis in response to treatment with isoproterenol) from what is not claimed (*i.e.*, nucleic acids having the structural characteristics recited in the claims, which are unable to confer an ability to maintain DNA synthesis in response to treatment with isoproterenol).

Although the application discloses a method by which nucleic acids having the recited function might be identified, An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. It is not sufficient to define DNA solely by its principal biological property (*i.e.*, it encodes a polypeptides that confers an ability to maintain DNA synthesis in response to treatment with isoproterenol) because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any DNA with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all DNA's that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before

it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)).

For these reasons, the only nucleic acids encoding polypeptides having an ability to maintain DNA synthesis in response to treatment with isoproterenol that are adequately described by the disclosure are those encoding the polypeptides set forth as SEQ ID NO: 2 and 4.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.
Examiner
Art Unit 1636

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER